DEC 2 0 2011

# CLYDESDALE® Spinal System
# 510(k) Summary
# November 2011

**I. COMPANY:**

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132

**II. CONTACT:**

Becky Ronner
Regulatory Affairs Specialist
Telephone: (901) 399-2757
Fax: (901) 346-9738

**III. PROPOSED PROPRIETARY TRADE NAME:**

CLYDESDALE® Spinal System

**IV. CLASSIFICATION NAMES:**

Intervertebral Body Fusion Device

**CLASS:**

II

**PRODUCT CODE:**

MAX (21 CFR 888.3080)

**V. PRODUCT DESCRIPTION:**

The CLYDESDALE® Spinal System is intended to help provide support in the intervertebral body space during fusion of vertebral bodies in the lumbar spine. This system is intended to be used with supplemental fixation.

The CLYDESDALE® Spinal System consists of PEEK™ OPTIMA™ LT-1 cages of various widths and heights, which include tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

**VI. INDICATIONS FOR USE:**

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may

also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

**VII. Summary of the Technological Characteristics:**

The purpose of this Special 510(k) submission is to seek clearance to incorporate additional size options into the CLYDESDALE® Spinal System family. The design, material and fundamental technology are the same as the current CLYDESDALE® Spinal System with minor dimensional changes.

**VIII. Identification of Legally Marketed Devices:**

The design features and indications for use for the subject CLYDESDALE® Spinal System are substantially equivalent to the following predicates:

- CLYDESDALE® Spinal System K100175 (S.E. 06/02/2010)
- PERIMETER™ Spinal System K090353 (S.E. 09/29/2009)
- CAPSTONE® Spinal System K073291 (S.E. 04/24/08)

**IX. Discussion of Non-Clinical Testing:**

Rationales based on Engineering Theoretical Analysis were completed using predicate testing that were performed in accordance with ASTMF 2077-03 "Test Methods for Intervertebral Body Fusion Devices" and ASTM F2267-04 "Standard Test Method for Measuring Load Induced Subsidence for the Intervertebral Body Fusion Device under Static Axial Compression". Data to support these rationales were provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

**X. Conclusion:**

A risk analysis was completed. Based on the risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject devices demonstrate substantial equivalence to listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 0 2011

Medtronic Sofamor Danek USA, Inc.
% Ms. Becky Ronner
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K113528
Trade/Device Name: Clydesdale® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: November 29, 2011
Received: November 30, 2011

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K113528

Device Name: CLYDESDALE® Spinal System

**Indications for Use:**

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Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113528